

Attorney Docket No. 4409.214-US
Serial No. 09/772,607
Filed: January 30, 2001
Inventors: Jonassen et al.
Via Facsimile No.: 517-273-8300

describes the "lower alkyl" groups of the '666 and '712 patents as being C₁-C₆ alkyls (see col. 1, lines 55-67 of USP 6,828,303).

Accordingly, since "lower alkyl" in the Habener '666 patent means C₁-C₆ alkyl, Habener cannot be held to anticipate claims 48-49 of the present application and withdrawal of this rejection is respectfully requested.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION OF THE CLAIMS

Claims 48-55 and 57-59 are rejected under the judicially created doctrine of obviousness type double patenting rejection over claims 1-3, 5-7, 14 and 15 of application 09/757,788 and claim 1 of the 10/285,079 application.

In reply, Applicants submit that these rejections are rendered moot by amendments to the claims that have been presented in the 09/757,788 and 10/285,079 applications.

In the 10/285,079 application, an Amendment filed May 6, 2005 cancelled claim 1 and presented claims directed to a GLP-1 derivative of formula I where *inter alia*

- 1) the GLP-1 derivative contains only one Lys and the Lys is not the N-terminal or C-terminal amino acid of the derivative, and
- 2) a lipophilic substituent of from 12 to 25 carbons is attached, optionally via a spacer, to the epsilon-amino group of the Lys.

Thus, the now pending claims of the 10/285079 application are directed to GLP-1 derivatives in which a lipophilic group is only attached to an internal amino acid of the GLP-1 peptide (i.e. no N-or C-terminal modifications). As the pending claims 48-59 in this application are directed to derivatives in which the lipophilic substituent is attached to the C-terminal amino acid of the GLP-1 peptide, the claims of the pending application are not obvious over the claims now pending in application 10/285,079 and withdrawal of this rejection is respectfully requested.

In the 09/757,788 application, an Amendment filed today, September 29, 2005, amends claim 1 in the '788 application to include the limitations of claims 14 and 17

Paged 1 - 4 Not Received

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and added a second independent claim (claim 27) to include the limitations of claims 20 and 24, where claims 17, 20 and 24 were not included by the Examiner in the present obviousness-type double patenting rejection. Thus the two independent claims in pending application 09/757788 now read as follows (with the newly added limitations being indicated by underline):

1. A liquid formulation suitable for pulmonary administration to a subject, said formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic substituent to said GLP-1 compound is optionally via a spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 um.
27. A dry formulation suitable for pulmonary administration to a subject, said formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic substituent to said GLP-1 compound is optionally via a spacer and wherein said formulation contains a mass median aerodynamic diameter of aerosol particles of less than 10 um.

Accordingly, in view of the above amendments to the claims in application 09/757,788, Applicants submit that the claims of the present application are not obvious over the claims now pending in application 09/757,788 and withdrawal of this rejection is therefore respectfully requested.

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The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Please charge any deficiencies or overpayment to Deposit Account
No.14-1447.

Respectfully submitted,

Date: September 29, 2005


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